

WHAT IS CLAIMED IS:

1                   1.       A method for inhibiting hyperplasia at a vascular treatment site, said  
2 method comprising:  
3                   directing vibrational energy at the vascular treatment site, wherein a scaffold  
4 structure has been implanted at said site, said scaffold structure being coated with a  
5 pharmaceutical agent which is released into the site over time, wherein directing vibrational  
6 energy comprises positioning a transducer on a catheter at the vascular treatment site and  
7 driving the transducer to emit the vibrational energy at the same time as the scaffold structure  
8 is implanted.

1                   2.       A method as in claim 1, wherein the vibrational energy is directed at  
2 the site at the time of implantation of the scaffold structure at a frequency and thermal index  
3 which will inhibit an acute phase of the hyperplasia, wherein the pharmaceutical agent is  
4 released over a period of at least one week following implantation to provide a longer term  
5 inhibition.

1                   3.       A method as in claim 2, wherein the vibrational energy does not cause  
2 significant cavitation in a wall of the blood vessel.

1                   4.       A method as in claim 2, wherein the vibrational energy causes a  
2 temperature rise below 10°C in the wall of the blood vessel.

1                   5.       A method as in claim 2, wherein vascular smooth muscle cells at least  
2 mostly remain viable but in a quiescent state in the neointimal layer after exposure to the  
3 vibrational energy.

1                   6.       A method as in claim 2, wherein migration of vascular smooth muscle  
2 cells into the neointimal layer is not substantially inhibited.

1                   7.       A method as in claim 2, wherein viability of vascular smooth muscle  
2 cells in a medial layer of the blood vessel is not significantly inhibited.

1                   8.       A method as in claim 2, wherein the vibrational energy has a frequency  
2 in the range from 20 kHz to 5MHz.

1                   9.       A method as in claim 8, wherein the intensity is in the range from 0.01  
2   W/cm<sup>2</sup> to 100 W/cm<sup>2</sup>.

1                   10.       A method as in claim 9, wherein the frequency and intensity are  
2   selected to produce a mechanical index at the neointimal wall in the range from 0.1 to 50.

1                   11.       A method as in claim 2, wherein the vibrational energy is directed  
2   against the implantation site with a pulse repetition frequency (PRF) in the range from 10 Hz  
3   to 10 kHz.

1                   12.       A method as in claim 2, wherein the energy is directed against the  
2   implantation site with a duty cycle in the range from 0.1 to 100 percent.

1                   13.       A method as in claim 1, wherein the vibrational energy is directed at a  
2   mechanical index selected to effect or promote release of the pharmaceutical agent from the  
3   implanted scaffold structure.

1                   14.       A method as in claim 13, wherein the frequency is in the range from  
2   20 kHz to 5 MHz and the intensity is in the range from 0.01 w/cm<sup>2</sup> to 100 W/cm<sup>2</sup>.

1                   15.       A method as in claim 1, wherein the vibrational energy is directed at a  
2   mechanical index selected to condition the vascular wall to enhance uptake of the  
3   pharmaceutical agent.

1                   16.       A method as in claim 15, wherein the frequency is in the range from  
2   300 kHz to 3 MHz and the intensity is in the range from 0.1 w/cm<sup>2</sup> to 20 W/cm<sup>2</sup>.

1                   17.       A method as in claim 1, further comprising directing vibrational  
2   energy at the vascular treatment site at least one additional time.

1                   18.       A method as in claim 17, wherein vibrational energy is directed at the  
2   vascular treatment site at least once at the time of implanting the scaffold structure and at  
3   least once one day or longer following implantation.

1                   19.       A method as in claim 1, wherein directing vibrational energy  
2   comprises externally generating vibrational energy and directing the vibrational energy  
3   transcutaneously to the vascular treatment site.

1                   20.     A method as in claim 19, wherein externally generating the vibrational  
2 energy comprises focusing an externally generated acoustic beam at the vascular treatment  
3 site.

1                   21.     A method as in claim 1, wherein the pharmaceutical agent comprises  
2 an agent selected from the group consisting of:  
3                   anti-coagulants (heparin, hirudin, GpIIB/IIIA inhibitors), anti-proliferation  
4 agents (paclitaxol, nitric oxide), anti-inflammatory agents (dexamethasone,  
5 methylprednisolone), antibiotics (rapamycin) and anti-oxidants (probucol).

1                   22.     A method as in claim 1, wherein the pharmaceutical agent comprises a  
2 nucleic acid sequence.

1                   23.     A method as in claim 22, wherein the nucleic acid sequence comprises  
2 genes expressing VEGF, thymidine kinase, eNOS and antisense oligonucleotides such as c-  
3 myc.

1                   24.     A method as in claim 1, wherein the pharmaceutical agent is directly  
2 layered onto the scaffold structure.

1                   25.     A method as in claim 1, wherein the pharmaceutical agent is dispersed  
2 in a biodegradable matrix applied to the surface of the scaffold structure.

1                   26.     A method as in claim 25, wherein the biodegradable matrix comprises  
2 polylactic acid or polyglycolic acid.